



2223 '00 JAN -6 A9 56

816 364-3777 • Fax 816 364-3778

Suitability Petition

December 30, 1999

Dockets Management Branch  
HFA-305, Room 123  
Food and Drug Administration  
Park Building  
12420 Parklawn Dr.  
Rockville, MD 20857

Dear Sir or Madam:

Enclosed is a Suitability Petition submitted in accord with FFDCA Section 512 (n) (3) on behalf of Phoenix Scientific, Inc., St. Joseph, MO 64503.

The Petition concerns a change in the salt form of the active drug substance in a generic Lincomycin-Spectinomycin Water Soluble Powder from the approved product, L-S 50 Water Soluble® Powder for chickens, approved under NADA 046-109, for Pharmacia & Upjohn. The requested change is from active drug substance Spectinomycin sulfate tetrahydrate for the approved to Spectinomycin dihydrochloride pentahydrate for the generic.

If there are any questions concerning this petition, or when you have completed your review, please call me at (816) 364-3777.

Sincerely:

Phoenix Scientific, Inc.

Robert D. Gunderson

Vice President, Regulatory Affairs

00P-0117

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## SUITABILITY PETITION

### Identification of Petitioner:

This Suitability Petition is submitted on behalf of Phoenix Scientific, Inc., (PSI) 3915 South 48<sup>th</sup> Street Terrace, St. Joseph, MO 64503 under Section 512 (n) (3) of the Federal Food, Drug, and Cosmetic Act.

### Action Requested:

PSI requests permission from the Commissioner to file an Abbreviated New Animal Drug Application (ANADA) containing a different form of the active drug substance than the approved product. The approved product, L-S 50 Water Soluble® Powder (NADA 046-109) contains Spectinomycin sulfate tetrahydrate equivalent to 33.3 grams spectinomycin. The proposed generic will contain Spectinomycin dihydrochloride pentahydrate equivalent to 33.3 grams spectinomycin. The amount of active ingredients administered per dose to the animal will be the same for both products.

The indications for the use of the generic product will be the same as for the approved product. A copy of the approved product labeling is enclosed.

### Statement of Grounds:

The proposed product contains the same active ingredient and has the same indications, cautions, and warnings as the approved product. Both products are for addition to drinking water for chickens. The products will differ only in the salt form of the active drug substance used, Spectinomycin dihydrochloride pentahydrate for the generic rather than Spectinomycin sulfate tetrahydrate for the approved product. The label copy will vary only as it relates to the different active drug substance.



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Environmental Impact:

The action of submitting and reviewing of this Suitability Petition will not normally be expected to have an environmental impact. Therefore, under 21 CFR 25.30(h), we request a categorical exclusion from the requirement to prepare an environmental assessment (EA), since, to the best of our knowledge, no extraordinary circumstances exist.

Economic Impact:

An "Economic Impact" analysis of this action will be provided upon request by the Commissioner.

Certification:

Attached is a statement that Phoenix Scientific, Inc. has included all information known to us, which is unfavorable to this Suitability Petition.

Approval to file an ANADA for this Propofol Injection based upon this Suitability Petition is requested.

Sincerely:

Phoenix Scientific, Inc.

Robert D. Gunderson

Vice President, Regulatory Affairs



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Certificate of Inclusion of Unfavorable Information

As the Chief Executive Officer for Phoenix Scientific, Inc., I certify that no unfavorable information related to this Suitability Petition has been withheld from the attached Suitability Petition.

December 30, 1999

Kevin M. Schinze  
President and CEO  
Phoenix Scientific, Inc.  
St. Joseph, MO 64503

NDC 0009-0108-06

**LS**<sup>50</sup>

WATER SOLUBLE® POWDER

LOT 85CPR

EXP 09/2003

**lincomycin-spectinomycin**

**Antibacterial and Antimycoplasmal**

**FOR USE IN CHICKENS ONLY**

**FOR DIRECTIONS-SEE REVERSE SIDE**



**This packet contains:**

Lincomycin hydrochloride, equivalent to lincomycin ..... 16.7 grams  
Spectinomycin sulfate tetrahydrate,  
equivalent to spectinomycin ..... 33.3 grams

**Total Antibiotic Activity 50.0 grams**

**NET WT. 2.65 OZ (75.0 grams)**



**Pharmacia & Upjohn**

### DIRECTIONS FOR USE

**INDICATIONS:** For use in chickens up to 7 days of age as an aid in the control of:

Airsacculitis caused by either *Mycoplasma synoviae* or *Mycoplasma gallisepticum* susceptible to lincomycin-spectinomycin.

Complicated Chronic Respiratory Disease (Air Sac Infection) caused by *Escherichia coli* and *M. gallisepticum* susceptible to lincomycin-spectinomycin.

**DOSAGE:** Provide 2 grams (g) antibiotic activity per gallon of drinking water. Administer as the sole source of water for the first 5 to 7 days of life.

#### ADMINISTRATION:

Amount of L-S 50	Amount of Drinking Water
1 packet	25 gallons
For proportioners delivering 1 ounce of solution per gallon of drinking water, dissolve contents of 5 packets in each gallon of proportioner solution.	

**IMPORTANT:** Chickens should consume water at the following approximate rate to insure intake of the required dose of lincomycin-spectinomycin indicated:

#### Broilers and Layer Replacements (Light and Heavy)

Age (Weeks)	Daily Water Intake Gallons/1000	Dosage Mg Antibiotic/Lb
1	5	50-65

**CAUTION:** Discard medicated drinking water daily and replace with fresh medicated drinking water.

**Warning:** Not for human use

**Store at room temperature**

813 526 003 **Restricted Drug—Use Only as Directed (California)**

Pharmacia & Upjohn Company • Kalamazoo, MI 49001, USA

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MAIL

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PB853948  
SAINT JOSEPH MO 6450



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